REMARKS

Entry of the foregoing, reexamination and reconsideration of the subject application are respectfully requested in light of the amendments above and the comments which follow.

As correctly noted in the Office Action Summary, claims 8-80 were pending, with claim 8 being withdrawn from consideration. By the present response, claims 9, 11, 23, 28, 30-32, 36, 38, 41, 43, 58-60 and 62 have been amended, claims 8, 20-22, 48-57, and 63-80 have been canceled, and claims 81-88 have been added. Thus, upon entry of the present response, claims 9-19, 23-47, 58-62, and 81-88 are pending and await further consideration on the merits.

Support for the foregoing amendments can be found, for example, in at least the following locations in the original disclosure: page 15, line 19 - page 16, line 13.

ELECTION/RESTRICTION

Applicants hereby confirm the oral election to prosecute the invention of species B. While Applicants continue to traverse the assertion that restriction is appropriate, claim 8 has been canceled by the present response, subject Applicants' right to pursue the subject matter of claim 8 in one or more divisional applications.

CLAIM REJECTIONS UNDER 35 U.S.C. §112

Claims 20-22 stand rejected under 35 U.S.C. §112, first paragraph, on the grounds set forth in paragraph 5 of the Official Action.

Claims 9-80 stand rejected under 35 U.S.C. §112, second paragraph, on the grounds set forth in paragraph 5 of the Official Action.

By the present response, Applicants have amended the claims in a non-narrowing manner to address the above-noted rejections. Therefore, reconsideration and withdrawal of the rejections are respectfully requested.

Claims 41 and 74 are rejected in paragraph 7 of the Official Action based on the use of the phrase "at least one of." By the present response, claim 41 has been amended to eliminate recitation of the phrase "at least one of," and claim 74 has been canceled. Thus, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 14, 26 and 53 have also been rejected in paragraph 7 of the Official Action on the grounds that "it is unclear what further limitations are set forth by claims . . . ." This rejection is respectfully traversed. First, by the present response, claim 53 has been canceled, thereby obviating its rejection. Claims 13 and 25 each contain a general recitation that the interstitial fluid analyte measurement means makes an ex vivo analyte concentration measurement, however, both claims 14 and 26 further specify, for instance, that it is the interstitial fluid analyte concentration measurement means that removes the interstitial fluid from the host. This additional limitation is not found in either claims 13 of 25. Thus, it is quite clear that both claims 14 and 26 further limit the claims from which they depend. Reconsideration and withdrawal of the rejection is respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. §102

Claims 9, 16-19, 30, 31, 35-37, 41, 42, 46-48, 55-57, 63-65, 68-70, 73-75 and 78-80 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent

No. 5,971,941 to Simons et al. (hereafter "*Simons et al.*") on the grounds set forth in paragraph 9 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

The present invention is directed to methods, devices and arrangements for the improved detection and analysis of an analyte. A method performed according to the principles of the present invention as set forth in amended claim 9. Amended claim 9 recites:

> *9. A method of monitoring the concentration of an analyte in a host or portion thereof over a given time period, said method comprising:*
> *(a) making a first analyte concentration measurement in said host or portion thereof at a first point in said time period using a first single use analyte concentration measurement means;*
> *(b) making a second analyte concentration measurement in said host or portion thereof at a second point in said time period using a second single use analyte concentration measurement means; and*
> *(c) making one or more additional analyte concentration measurements during said time period using one or more additional single use analyte concentration measurement means;*
> *wherein said analyte concentration measurements of (a) and (b) are made according to a selected scheduling mode to monitor the concentration of said analyte in said host or portion thereof over said given time period.*

A device constructed according to alternative aspects of the present invention as set forth in amended claim 30:

> *30. A device for use in monitoring the concentration of an analyte in a host or portion thereof over a given period of time, said device comprising:*
> *(a) at least a first and a second single use analyte concentration measurement means;*
> *(b) a timing device comprising a predetermined timetable; and*
> *(c) an activation means for selectively activating said first and second analyte concentration measurement means according to the predetermined schedule.*

A system constructed according to further principles of the present invention is defined by amended claim 36:

> *36. A system for use in monitoring the concentration of an analyte in a host or portion thereof over a given period of time, said system comprising:*
> *(a) a removable cartridge comprising at least a first and a second single use analyte concentration measurement means; and*
> *(b) a device into which said cartridge may be inserted, wherein said device comprises a timing device comprising a predetermined schedule; and an activation means for selectively activating said first and second measurement means of said cartridge according to the predetermined schedule.*

A kit performed according to yet another aspect of the present invention is defined by amended claim 41:

> *41. A kit for use in monitoring the concentration of an analyte in a host or portion thereof over a given period of time, said kit comprising:*
> *(a) a removable cartridge comprising at least a first and a second single use analyte concentration measurement means; and*
> *(b) a device into which said cartridge may be inserted, wherein said device comprises a timing device comprising a predetermined schedule; and an activation means for selectively activating said first and second measurement means of said cartridge according to the predetermined schedule.*

Simons et al. is directed to an integrated system and method for sampling blood from the skin of a patient for analysis. The apparatus includes a cartridge. However, *Simons et al.* fails to anticipate either claims 9, 30, 36, or 41, or any claim depending therefrom.

As evident from the above, claim 9 requires the "analyte concentration measurements of (a) and (b) are made according to a selected scheduling mode . . . ." By contrast, *Simons et al.* contains no disclosure whatsoever regarding a method of monitoring the concentration of an analyte according to a selected

scheduling mode. In fact, the grounds for rejection, as set forth in paragraph 9 of the Official Action admit this much. However, it is nonetheless asserted that:

> As for limitations regarding the predetermined time periods and predetermined schedule and schedule mode, any persons needing to use such equipment has a set schedule for taking such readings and then retaking them on a set schedule based upon many parameters, such as what the previous reading was, eating times, etc. Thus all of the claim limitations drawn to scheduling and time periods are inherently met during the use of the system.

First, it is important to recognize that the above stated grounds for rejection are clearly based upon the principle of inherency. As such, it is incumbent upon the Examiner to demonstrate that those features not expressly disclosed in the prior art must necessarily occur. The presence of the missing features cannot be established by possibilities, it invariably must happen. See, MPEP §2112.

Applicants respectfully traverse the assertion that *Simons et al.* inherently discloses the above quoted aspect of amended claim 9. In particular, Applicants traverse the assertion that "any person needing to use such equipment has a set schedule for taking such readings." In fact, quite the opposite has been observed in reality. Although recommendations have been set forth concerning the number of times per day by which glucose or other analyte levels could or should be monitored, it has nonetheless been documented that adherence to these guidelines is generally poor. In fact, testing is not performed, in reality, according to any "set schedule" by diabetics. See, e.g. Exhibit A. Thus, Applicants respectfully submit that the above-quoted aspect of the above-quoted limitation appearing in amended claim 9 is not inherent to the use of the device set forth by *Simons et al.*

To reemphasize a key point, *Simons et al.* contains no disclosure whatsoever concerning how frequently the device should be used by the user to test for analyte

concentration levels, such as glucose. Reconsideration and withdrawal of the rejection of claim 9 is respectfully requested.

As evident from the above, claim 30 is directed to a device which includes "a timing device comprising a predetermined time table . . . ." *Simons et al.* clearly fails to disclose at least this aspect of amended claim 30. Thus, reconsideration and withdrawal of the rejection is respectfully requested.

As evident from the above, amended claim 36 is directed to a system which includes "a timing device comprising a predetermined schedule . . . ." By contrast, *Simons et al.* clearly fails to disclose any such timing device. Therefore, reconsideration and withdrawal of the rejection is respectfully requested.

Similarly, amended claim 41 is directed to a kit which includes "a timing device comprising a predetermined schedule . . . ." By contrast, *Simons et al.* fails to disclose any such timing device. Thus, reconsideration and withdrawal of the rejection is respectfully requested.

The remaining claims depend either from claims 9, 30, 36 or 41. Thus, these claims are also distinguishable over *Simons et al.* for at least the same reasons noted above.

CLAIM REJECTIONS UNDER 35 U.S.C. §103

Claims 10-15, 32-34, 38-40, 43-45, 49-54, 66, 67, 71, 72, 76 and 77 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Simons et al.* as applied to claims 9, 30, 36, 41, 48, 63, 69 and 74 above, and further in view of U.S. Patent No. 6,183,489 to Douglas et al. (hereafter "*Douglas et al.*") on the grounds set

forth in paragraph 11 of the Official Action. For at least the reasons noted below, this rejection should be withdrawn.

A method of monitoring interstitial fluid according to the principles of the present invention set forth in amended claim 23. Amended claim 23 recites:

> *23. A method of monitoring the concentration of glucose in interstitial fluid of a host over a given time period, said method comprising:*
> *(a) making a first interstitial fluid glucose concentration measurement at a first point in said time period using a first single use interstitial fluid glucose concentration measurement means;*
> *(b) making a second interestitial fluid glucose concentration measurement at a second point in said time period using a second single use interestitial fluid glucose concentration measurement means; and*
> *(c) making one or more additional interstitial fluid glucose concentration measurements during said time period using one or more additional single use interestitial fluid glucose concentration measurement means; wherein said interstitial fluid glucose concentration measurements (a) and (b) are made according to a predetermined schedule to monitor the concentration of interstitial fluid glucose over said given time period.*

According to a further aspect, a method of monitoring interstitial fluid according to a predetermined schedule is set forth in amended claim 58. Amended claim 58 recites:

> *58. A method of monitoring the concentration of an analyte in a host over a given time period, said method comprising:*
> *(a) making a first analyte concentration measurement at a first point in said time period using a first single use analyte concentration measurement means;*
> *(b) making a second analyte concentration measurement at a second point in said time period using a second single use analyte concentration measurement means; and*
> *(c) making one or more additional concentration measurements during said time period using one or more additional single use analyte*

concentration measurement means; wherein said analyte concentration measurements are made according to a predetermined schedule selected from two or more predetermined schedules selected by the user or medical personnel to monitor the concentration of interstitial fluid glucose over said given time period.

First, with regard to those claims depending from either claims 9, 30, 36 or 41, *Douglas et al.* is cited as allegedly teaching obtaining measurement results from interstitial fluid. However, even if the teachings of *Douglas et al.* were applied exactly as suggested in the grounds for rejection, the claimed invention would not result. Namely, *Douglas et al.* fails to cure the deficiencies noted above in connection with the above-mentioned independent claims and those features which are missing from the disclosure of *Simons et al.* Moreover, the grounds for rejection fails to establish a *prima facie* case of obviousness. Namely, given the radically different constructions of the devices of *Douglas et al.* and *Simons et al.*, it is not apparent how one of ordinary skill in the art would incorporate the functionality described by *Douglas et al.* into the radically different device of *Simons et al.* For example, the device of *Simons et al.* is in the form of a cartridge. The device of *Douglas et al.* is not. The actuation mechanisms for *Douglas et al.* and *Simons et al.* are also radically different. This has a direct effect on the sampling depth, which is an important factor in obtaining a sample of interstitial fluid. It is respectfully submitted that the proposed modification of *Simons et al.* with *Douglas et al.* would require a complete reconstruction of one or more of the devices, thus constituting an impermissible change in the principle mode of operation of the device of *Simons et al.*, if not *Douglas et al.* See, e.g., M.P.E.P. §2143.01. Thus, for at least this additional reason, the grounds for rejection are improper.

With respect to claim 23, in addition to the above noted reasons, *Simons et al.* in view of *Douglas et al.* fail to render the method recited therein obvious. As evident from the above, claim 23 recites a method wherein "said interstitial fluid glucose concentration measurements (a) and (b) are made according to a predetermined schedule . . . ." By contrast, as explained above, *Simons et al.* fails to contain any such disclosure, as admitted in the grounds for rejection. Moreover, this aspect of the presently claimed invention is also not inherent to *Simons et al.* for the same reasons explained above. The applied teachings of *Douglas et al.* do nothing to cure this deficiency. Thus, even if the proposed combination were appropriate, the method recited in claim 23 would not result. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 58 is directed to a method which includes, *inter alia*, "said analyte concentration measurements are made according to a predetermined schedule selected from two or more predetermined schedules selected by the user or medical personnel. . . ." It is respectfully submitted that *Simons et al.* clearly fails to contain any such corresponding disclosure. Moreover, contrary to the assertions contained in the grounds for rejection, the above quoted aspect of the method of claim 58 is not inherent to the disclosure and/or use of the device of *Simons et al.* See, e.g., Exhibit A. Also, see the discussion above concerning the anticipation rejection based on the disclosure of *Simons et al.* Thus, even if the proposed combination were appropriate, the claimed invention would not result. Reconsideration and withdrawal of the rejection is respectfully requested.

The remaining claims depend from either claim 23 or claim 58. Thus, these claims are also distinguishable over the applied prior art for at least the same reasons noted above.

OBVIOUSNESS-TYPE DOUBLE PATENTING

Claims 9-12, 15-17, 23, 24, 27, 30, 32-36, 38-41, 43-45, 47 and 74-78 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 78-82, 87 and 90-94 of U.S. Patent No. 6,923,764 on the grounds set forth in paragraph 14 of the Official Action. The grounds for rejection are respectfully traversed. It is asserted in paragraph 14 of the Official Action that the above listed claims of the present application are not patentable over the claims of prior U.S. Patent No. 6,923,764 on the grounds that "any apparatus or method meeting the limitations of the patent would necessarily meet those of the instant application." However, this assertion is inadequate to establish a *prima facie* case of obviousness-type double patenting. It is the claims of the application and patent which are to be compared, not a comparison of a hypothetical infringement of either set of claims by a hypothetical device or method. Thus, the grounds for rejection clearly fail to establish a *prima facie* case of obviousness-type double patenting. Moreover, in order to establish a *prima facie* case of obviousness-type double patenting, the grounds for rejection must establish that either each and every feature recited in the present application are present either expressly or inherently, or would have been obvious to one of ordinary skill in the art, in light of the claims of the previous patent. This requirement is essentially the same as establishing a *prima facie* case of unpatentability based on novelty or obviousness. It is respectfully submitted that the grounds for rejection fall far short of satisfying these

requirements. Therefore, reconsideration and withdrawal of the rejection is respectfully requested.

In addition, by the present response, the claims of the present application have been amended. The grounds for rejection fail to consider the current amendments to the claims of the present application and its potential effect on any alleged double patenting rejection.

NEW CLAIMS

By the present response, Applicants have added claims 81-88, which depend upon claims 9 or 23. Thus, claims 81-88 are also distinguishable over the applied prior art for at least the same reasons set forth above in connection with the rejections of claims 9 and 23.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is earnestly solicited. Should the Examiner feel that any issues remain, it is requested that the undersigned be contacted so that any such issues may be adequately addressed and prosecution of the instant application expedited.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: February 3, 2009 By: _____

Scott W. Cummings
Registration No. 41,567

P.O. Box 1404
Alexandria, VA 22313-1404
703 836 6620

syndrome" (4). Both incidents took place during the first half of pregnancy when, in particular, nocturnal hypoglycemic events are known to be prevalent. Whether such a pregnancy predisposes diabetic mothers to dead-in-bed syndrome or triggers subsequent mechanisms is equivocal; regardless, these deaths may amount to 24% of all deaths in young diabetic patients (4). However, in ours and other studies (1), these deaths might have been at least theoretically preventable, and we feel that first-trimester care of preganant diabetic women must focus on hypoglycemia.

PEKKA J. LEINONEN, MD
VILHO K. HIILESMAA, MD
RISTO J. KAAJA, MD
KARI A. TERAMO, MD

From the Department of Obstetrics and Gynecology, University Central Hospital of Helsinki, Helsinki, Finland.

Address correspondence and reprint requests to Pekka Leinonen, MD, Department of Obstetrics and Gynecology, P.O.B. 140, Helsinki, FIN-00029, Finland. E-mail: pekka.leinonen@hus.fi.

References

1. Gabbe S-G, Mestman J-H, Hibbard L-T: Maternal mortality in diabetes mellitus: an 18-year survey. *Obstet Gynecol* 48: 549–551, 1976
2. Cousins L: Pregnancy complications among diabetic women: review 1965–1985. *Obstet Gynecol Surv* 42:140–149, 1987
3. Lounamaa R: *Mortality in Finnish Patients With Insulin-Dependent Diabetes Mellitus*. Helsinki, The Social Insurance Institution, 1993
4. Sovik O, Thordarson H: Dead-in-bed syndrome in young diabetic patients. *Diabetes Care* 22 (Suppl. 2):B40–B42, 1999

Lack of Compliance With Home Blood Glucose Monitoring Predicts Hospitalization in Diabetes

Home capillary blood glucose (CBG) monitoring is the standard of care for patients with diabetes (1,2). Patients with type 1 diabetes should monitor their CBG concentration at least three or four times daily, and patients with type 2 diabetes should probably monitor their CBG concentration at least twice a day (1). Nevertheless, up to 67% of patients with diabetes fail to routinely monitor their CBG levels (3). Although the relationship between rigorous home blood glucose monitoring and improved glycemic control is well-established, determinants of compliance with home blood glucose monitoring recommendations are not known. Reported here are the results of a marketing survey exploring attitudes and behaviors surrounding compliance with home CBG monitoring.

My group has previously published a study examining the efficacy of a laser skin perforator for the attainment of capillary blood samples for home CBG monitoring (4). In response to the large number of telephone inquiries received, the manufacturer of this device (Lasette Laser Skin Perforator; Cell Robotics, Albuquerque, NM) mailed out a brief questionnaire examining current home blood glucose monitoring practices and attitudes about this activity during the years 1999 and 2000. Of 6,600 questionnaires mailed, 1,895 (29%) were returned, and the data were analyzed using SAS. Respondents were entered into a drawing for a free laser skin perforator. This study was exempted from informed consent requirements by the University of New Mexico Human Research Review Committee.

Data collected from the questionnaires included the duration of diabetes, the number of times per day the patient had been instructed to monitor CBG by a healthcare provider, the number of times per day the patient actually monitored CBG, the reason the patient monitored CBG less frequently than recommended (if applicable), the number of hospitalizations and physician's office visits over the past two years, and the presence or absence of continuous subcutaneous insulin infusion (CSII) therapy.

The mean duration of diabetes (means ± SD) among respondents was 16.2 ± 13.2 years. The mean recommended frequency of CBG testing was 3.9 ± 2.1 tests per day, whereas the actual reported frequency of testing was 3.7 ± 2.6 tests per day ($P < 0.001$ by paired t test). CSII therapy was used by 256 (14%) of the respondents, and both the recommended frequency of CBG testing (6.1 ± 2.4 vs. 3.6 ± 1.8 tests per day, $P < 0.001$) and the actual frequency of testing (6.3 ± 2.9 vs. 3.3 ± 2.3 tests per day, $P < 0.001$) was significantly greater in the CSII patients than in the non-CSII patients, as determined by unpaired t test.

There were 15,564 visits to physician's offices among 1,871 patients (8.3 ± 6.8 visits per patient), and there were 698 hospitalizations among 339 patients (0.4 ± 1.3 hospitalizations per patient) over the previous two years. Reported healthcare utilization rates were compared as a function of reported compliance with home CBG monitoring recommendations. For this purpose, a compliance term was devised using the difference between actual and recommended testing, with values <0 denoting noncompliance. Compliance improved with increasing duration of diabetes (OR 1.01 per year, 95% CI 1.003–1.018, $P = 0.009$ by logistic regression). Compliance was negatively related to the number of physician's office visits ($P = 0.03$) and to the number of hospitalizations, as determined by regression analysis ($P = 0.004$). Post hoc testing revealed that patients with more than two hospitalizations over the past two years were less compliant with CBG monitoring than patients with less than two hospitalizations (compliance scores: −0.21 ± 1.72, −0.44 ± 1.74, and −0.72 ± 1.54, respectively, for fewer than two, two, and more than two hospitalizations; $P = 0.02$). Finger soreness was the most common reason given for self-reported noncompliance with testing recommendations ($n = 492$), followed by pain ($n = 428$), inconvenience ($n = 347$), fear of needles ($n = 117$), and "other" (including cost; $n = 96$). Interestingly, fear of needles was reported as a reason for noncompliance by 6% of all respondents and by 14% of the noncompliant respondents ($P < 0.001$ by χ^2).

Limitations of these data include the fact that they are derived from a self-reported sample of convenience and not a randomized study. Moreover, some potentially important information, such as sex and type of diabetes, was not captured by the questionnaire. Nevertheless, these data demonstrate that *1*) there is wide variation in the perceived recommended frequency of CBG monitoring, *2*) compliance with home CBG monitoring is often less than recommended, *3*) rates

of healthcare utilization are increased among patients who are noncompliant with CBG monitoring, and 4) pain and soreness are the most common reasons for noncompliance with CBG monitoring. Clear guidelines should be developed for CBG monitoring frequency in patients with diabetes so that a consistent message is delivered by diabetes care providers. Moreover, compliance with CBG monitoring should be assessed at patient visits, and its importance should be reinforced. Strategies to improve compliance with CBG monitoring, including reducing the pain or perceived pain associated with the procedure, should be developed and implemented with the aim of improving the acceptability of this essential component of diabetes management. Finally, needleless methods of blood sampling for CBG monitoring may also improve compliance in patients with needle phobia (5).

Acknowledgments— This research was supported by a grant from Cell Robotics, Albuquerque, NM, and by the University of New Mexico General Clinical Research Center (NIH NCRR GCRC Grant 5 M01-RR00997).

MARK R. BURGE, MD

From the Department of Medicine/Endocrinology, University of New Mexico Health Sciences Center, Albuquerque, New Mexico.

Address correspondence and reprint requests to Mark R. Burge, MD, Assistant Professor of Medicine, University of New Mexico Health Sciences Center, Department of Medicine/Endocrinology - 5ACC, Albuquerque, NM 87131. E-mail: mburge@salud.unm.edu.

References

1. American Diabetes Association: Standards of medical care for patients with diabetes mellitus (Position Statement). *Diabetes Care* 24 (Suppl. 1):S33–S43, 2001
2. Hirsch IB, Farkas-Hirsch R, Skyler JS: Intensive insulin therapy for type 1 diabetes (Review). *Diabetes Care* 13:1265–1283, 1990
3. Harris MI, Cowie CC, Howie LJ: Self-monitoring of blood glucose by adults with diabetes in the United States population. *Diabetes Care* 16:1116–1123, 1993
4. Burge MR, Costello DJ, Peacock SJ, Friedman NM: Use of a laser skin perforator for determination of capillary blood glucose yields reliable results and high patient acceptability. *Diabetes Care* 21:871–873, 1998
5. Zambanini A, Feher MD: Needle phobia in type 1 diabetes mellitus. *Diabet Med* 14:321–323, 1997

Seasonal Variation of Glycemic Control in Type 2 Diabetic Patients

Medical nutrition therapy is integral to diabetes care and management (1). Balance between dietary intake and energy consumption through daily physical activities is the most influential factor in the glycemic control of type 2 diabetic patients. The nutritional prescription made for a diabetic individual is usually determined by taking into consideration the expected physical activity, diabetes complication(s), and age. The dietary advice based on this prescription seems to be valid in many cases for at least a few years; for some diabetic patients, its validity is lifelong. Such a dietary prescription is made by an implied understanding that eating habits and physical activity do not change throughout the year. Here, we show a seasonal variation of HbA_{1c} levels in type 2 diabetic patients.

Fukushima province is a large agricultural area surrounded by mountains, and it has a relatively low population density compared with central Japan. The climate is typical of any valley area; the people experience very warm and humid Asian summers (>34°C) and icy cold winters from January to early March. Generally, the people here are active outdoors, with some patients engaging in field work from spring to fall, but not as frequently during winter. During winter, when it gets dark around 4:00 P.M. and the roads are icy and slippery, the people customarily enjoy salty meals prepared in a pot and alcoholic beverages.

We calculated the mean HbA_{1c} levels of 39 type 2 diabetic patients (27 women and 12 men, mean age 65.6 years) in each month. The mean HbA_{1c} level was elevated by ~0.5% in winter compared with the period between spring and autumn, ranging from 6.42 ± 0.65% (mean ± SD) in July to 6.96 ± 0.90% in March, $P < 0.01$.

This observed seasonal variation in HbA_{1c} levels is likely caused by an increased dietary calorie intake and decreased physical activity during the cold winter months. It is rare for doctors to prescribe different nutritional prescriptions in winter, and we did not find any diabetes textbook that discussed this seasonal change in lifestyle. It seems reasonable for diabetologists and dietitians to modify the nutritional prescription for those diabetic patients whose opportunities for physical exercise are reduced during the winter months.

HAJIME ISHII, MD[1]
HODAKA SUZUKI, MD[1]
TSUNEHARU BABA, MD[1]
KEIKO NAKAMURA, BS[2]
TSUYOSHI WATANABE, MD[1]

From the [1]Third Department of Internal Medicine and the [2]Division of Clinical Nutrition, Fukushima Medical University, Fukushima, Japan.

Address correspondence to Dr. Hajime Ishii, Fukushima Medical University, 1 Hikarigaoka, Fukushima 960-1295, Japan. E-mail: baba@fmu.ac.

References

1. American Diabetes Association: Nutrition recommendations and principles for people with diabetes mellitus (Position Statement). *Diabetes Care* 24 (Suppl. 1):S44–S47, 2001

Is There a Predisposition to Intestinal Parasitosis in Diabetic Patients?

Although intestinal parasites usually create benign diseases, sometimes they may cause complications with high mortality and morbidity (1,2). It is known that diabetic patients are more susceptible to bacterial infections. Decreased arterial perfusion, neuropathy, and suppressed immune response in diabetes aggravate the frequency and severity of infectious diseases (3). Lymphocyte and polymorphonuclear leukocyte functions are altered (4). The most prominent alteration is the phagocytic functions of polymorphonuclear leukocytes (5,6). It has also been reported that candidal infections occur more frequently in diabetic